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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,455	03/10/2000	Jurgen Engel	PM 264671	5040

909 7590 11/26/2002
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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application N .

09/523,455

Applicant(s)

ENGEL ET AL.

Examin r

Shaojia A. Jiang

Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 November 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 1 and 3-24.Claim(s) withdrawn from consideration: none.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Advisory Action

This Office Action is a response to Applicant's amendment and response after FINAL filed on November 7, 2002.

It is noted that Applicant indicates that the response in Paper No. 9 is filed on October 25, 2001, not February 28, 2002 as stated in the previous Office Action (may 7, 2002). The examiner suggests Applicant to file the receipt stamped by the OIPE, dated October 25, 2001 in order to clear the record, although the examiner does recall the telephone conversation in late February 2002 with Mr. Michael Sanzo regarding the missing amendment.

5. Applicant's remarks filed February 1, 2002 with respect to the rejection of claims 1 and 3-24 made under 35 U.S.C. 103(a) as being unpatentable over Engel et al. and Albano et al. and Felberbaum et al. and Garfield (5,470,847) in view of Deghenghi (5,945,128) and Rabasseda et al. and Kent (4,016,259) have been fully considered but are unpersuasive for reasons of record stated in the Final Office Action dated may 7, 2002.

Again, Applicant's arguments that the cited references, either alone or in combination do not render the presently claimed invention unpatentable have been considered but are not found persuasive.

As discussed in the Final Rejection, the instant LHRH-antagonists such as teverelix, antide, and abarelix are known to be LHRH-antagonists and known to be useful in the methods of controlled ovarian stimulation and assisted reproductive

techniques and of the treatment of infertility according to Engel et al., Albano et al., Felberbaum et al., Deghenghi and Rabasseda et al. Thus, each step in the instant claimed method is known in the prior art. Further, the particular estrogen herein, mestranol, in oral contraceptive preparations in combination with progestogen are well known contraceptive agents and also known broadly to be useful in the therapeutic management of infertility according to the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining these particular agents known useful for the same purpose in a composition to be administered would produce additive therapeutic effects to improve the treatment of in the therapeutic management of infertility, absent evidence to the contrary.

Since all active composition components herein are known to useful in the therapeutic management of infertility, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected based on the well settled principle set forth *In re Kerkhoven* regarding combination inventions.

Applicant's results of the instant method (program) in the specification at page 4-5 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. The results provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no side-by-side comparison with the closest prior art. Therefore, the evidence presented in

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specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.


Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
November 20, 2002


SREENI PADMANABHAN
PRIMARY EXAMINER
11/24/02